JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Dennis Granata

(b) County of Residence of First Listed Plaintiff Washoe County, NV
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Sindhu Daniel, 3102 Oak Lawn Ave #1100, Dallas, TX 75219
(214) 521-3605

DEFENDANTS

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; BAYER AG; BAYER and PHARMA AG

County of Residence of First Listed Defendant Morris County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. Sec. 1332

Brief description of cause:
Personal injuries due to defective products

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
12/13/2017

SIGNATURE OF ATTORNEY OF RECORD
Sindhu Daniel

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 2010 West Moana Street, Reno, NV 89509

Address of Defendant: Bayer Healthcare Pharmaceuticals, Inc., 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045

Place of Accident, Incident or Transaction: Nevada

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☑

Does this case involve multidistrict litigation possibilities? Yes☑ No☐

RELATED CASE, IF ANY: MDL No. 2642; IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION.

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☑
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☑ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☑
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☑

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
    (Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☑ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
   (Please specify) _____

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Sindhu Daniel, counsel of record do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: December 13, 2017 Sindhu Daniel (Attorney-at-Law) I. D. #77466 (Attorney I.D.#)

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: December 13, 2017 Sindhu Daniel (Attorney-at-Law) I.D. #77466 (Attorney I.D.#)

CIV. 609 (5/2012)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

DENNIS GRANATA	:	CIVIL ACTION
v.	:	
BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; BAYER AG; and BAYER PHARMA AG.	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (✔)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

December 13, 2017	Sindhu Daniel	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
214-521-3605	214-520-1181	sdaniel@baronbudd.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DENNIS GRANATA, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICLAS, INC.; BAYER CORPORATION, BAYER AG, and BAYER PHARMA AG; Defendants.	Case No.: _____ **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL** **1. Strict Liability** **2. Product Liability – Failure to Warn** **3. Negligence** **4. Breach of Express Warranty** **5. Breach of Implied Warranty** **6. Fraud** **7. Negligent Representation** **8. Fraudulent Concealment**

Plaintiff, Dennis Granata, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges the following:

INTRODUCTION

1. This case involves the prescription drug Cipro® (also known as ciprofloxacin), which is designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and/or sold by Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Corporation, Bayer AG and Bayer Pharma AG. Cipro® in any of its forms, shall herein be referred to as "Cipro."

2. Plaintiff maintains that Cipro is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with their use.

PARTIES

3. Plaintiff, Dennis Granata, is a natural person and is a resident and citizen of Washoe County, Nevada. Plaintiff brings this action for personal injuries sustained by the use

of Cipro. As a direct and proximate result of being prescribed and ingesting Cipro, Plaintiff developed irreversible peripheral neuropathy, symptoms of peripheral neuropathy, and other symptoms associated with adverse reactions to fluoroquinolones.

4. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer Healthcare") is a Delaware corporation that has its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045.

5. Defendant Bayer Healthcare has transacted and conducted business within the States of Nevada and Pennsylvania.

6. Defendant Bayer Healthcare has derived substantial revenue from goods and products used in the States of Nevada and Pennsylvania.

7. Defendant Bayer Healthcare expected or should have expected its acts to have consequences within the States of Nevada and Pennsylvania, and derived substantial revenue from interstate commerce.

8. Defendant Bayer Healthcare was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Cipro.

9. Defendant Bayer Corporation ("Bayer Corp.") is an Indiana corporation that has its principal business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

10. Defendant Bayer Corp. has transacted and conducted business within the States of Nevada and Pennsylvania.

11. Defendant Bayer Corp. has derived substantial revenue from goods and products used in the States of Nevada and Pennsylvania.

12. Defendant Bayer Corp. expected or should have expected its acts to have

consequences within the States of Nevada and Pennsylvania, and derived substantial revenue from interstate commerce.

13. Defendant Bayer Corp. was engaged at all relevant times in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Cipro.

14. As used herein, "Defendants" includes all named Defendants.

15. Defendants are authorized to do business in Nevada and Pennsylvania and derive substantial income from doing business in these states.

16. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities within Nevada and Pennsylvania, thus invoking the benefits and protections of its laws.

17. Upon information and belief, the Defendants did act together to design, sell, advertise, manufacture and/or distribute Cipro, with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

18. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants. Defendants are all either incorporated and/or have their principal place outside of the state in which the Plaintiff resides.

19. The amount in controversy between Plaintiff and Defendants exceeds $75,000, exclusive of interest and cost.

20. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

21. Venue is proper within this district pursuant to 28 U.S.C. § 1391 in that

Defendants conduct business in the state of Pennsylvania and Nevada and are subject to personal jurisdiction in this district. Furthermore, Defendants sell, market, and/or distribute Cipro within this district. Also, a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL ALLEGATIONS

22. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drugs Cipro.

23. Plaintiff was prescribed Cipro on or about January 2004 and used it as directed.

24. Shortly after ingesting the drug and using it as directed, Plaintiff developed symptoms of peripheral neuropathy, weakness, loss of balance, drop foot, tingling and burning sensation in his arms and legs.

25. Cipro is a broad-spectrum fluoroquinolone antibiotics used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

26. Cipro is a member of the quinolone class of antibiotics. Quinolones are divided into four generations based on their spectrum of antimicrobial activity.

27. The 1st generation of non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

28. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

29. Fluoroquinolones have long been associated with serious side effects. Indeed,

many fluoroquinolones have been removed from the United States market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

30. Cipro was approved by the United States Food and Drug Administration (hereinafter, "FDA") in October 1987 for use in the United States, and is the brand name for the antibiotic ciprofloxacin.

31. In 1999 Cipro amassed more than one billion ($1,000,000,000) in sales in the United States, the first Bayer product to ever do so.

32. In 2002, Cipro became the best-selling antibiotic in the world.

33. Defendant Bayer Healthcare has indicated on its website that Cipro is the "gold standard" treatment for many infections, with an "extensive and unprecedented safety profile" that included being "studied and documented in over 37,000 publications."

34. However, the scientific evidence has established a clear association between Cipro and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

35. Defendants knew or should have known that Cipro is associated with an increased risk of developing irreversible peripheral neuropathy.

36. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of Cipro concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish,

diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

37. The warning label for Cipro during the period from September 2004 through August 2013 mislead Plaintiff and Plaintiff's treating physician by incorrectly advising patients and physicians that peripheral neuropathy associated with Cipro was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible.

38. Though this injury can be significant and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Cipro label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

39. Additionally, Defendants failed to disseminate a "Dear Doctor" letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Cipro to physicians.

40. Despite their knowledge that Cipro was associated with an elevated risk of permanent nerve damage, Defendants' promotional campaign was focused on Cipro's purported "safety profile."

41. As early as 1992, there was evidence of an association between fluoroquinolones and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.[1]

[1] Aoun M., Jacquy C, Debusscher L, Bron D, Lehert M, Neol P, et al. Peripheral neuropathy associated with fluoroquinolones (letter). Lancet. 1992; 340:127.

42. Four years later, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.[2]

43. In 2001, Jay S. Cohen published a research study in the United States entitled "Peripheral Neuropathy Associated with Fluoroquinolones."

44. The Cohen paper studied forty-five (45) patients and expressed concerns over a link between permanent peripheral neuropathy and fluoroquinolones.[3]

45. In 2002 and 2003, Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

46. A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning Levaquin and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

47. In 2004, the Levaquin label was amended to include the following statement regarding peripheral neuropathy in the Warnings section:

> **Peripheral Neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesia, hypoesthesia, dysesthesias and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

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[2] Hedenmalm, K. and Spigset, O. Peripheral sensory disturbances related to treatment with fluoroquinolones. J Antimicrob Chemother 1996;37(4):831-7.

[3] Cohen, JS. Peripheral neuropathy associated with fluoroquinolones. Ann Pharmacother 2001;35:1540. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy, and concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information." *Id.*

48. Thus, rather than warning patients and physicians that the use of Levaquin may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and, in any event, could be avoided by simply discontinuing the drug upon the onset of certain symptoms.

49. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Levaquin instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which Plaintiff presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with Levaquin.

50. The failure of Defendants to include appropriate warnings in the label, as published to the medical community, also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

51. Despite Defendants' knowledge and failure to adequately warn Plaintiff and his physicians of the above, Defendants continue to market Levaquin as a first line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.

52. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warnings regarding peripheral nerve damage were inadequate. On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in the Levaquin label, and which removed the statement that nerve damage occurred only in "rare" cases:

> Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesia, hypoesthesia, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including Levaquin. Symptoms may occur soon after initiation of Levaquin and may be irreversible. Levaquin should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation

including light touch, pain, temperature, position sense, and vibration sensation.

53. Notwithstanding this updated 2013 label change, the Levaquin label remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy. For instance, the Levaquin label currently states under the "Warnings and Precautions" section of the first page: Peripheral neuropathy: discontinue immediately if symptoms occur in order to *prevent irreversibility* (5.8)." This statement implies to physicians and patients that, if the patient stops using the drug immediately after symptoms occur, the symptoms are reversible. However, in section 5.8, the label states that "Symptoms [of peripheral neuropathy] may occur soon after initiation of LEVAQUIN® and *may be irreversible*." This later statement conflicts with the earlier statement by implying that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label that that the symptoms of peripheral neuropathy are reversible if the drug is stopped immediately after symptoms occur, but to advise physicians and patients in another section of the label that symptoms may be irreversible no matter whether they stop taking the medication immediately upon experiencing symptoms.

54. According to a study conducted by Ayad Ali, RPh, PhD, and published in *Annals of Epidemiology* in January 2014, between 1997 and 2012 there were 539 reports of peripheral neuropathy among 46,257 adverse event reports submitted for fluoroquinolone antibiotics to the FDA's Adverse Event Reporting System.[4] A pharmacovigilance analysis of this data further underscored the link between systemic exposure to fluoroquinolones and peripheral neuropathy and showed a potential association with more severe forms of nerve damage.[5] The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for Levaquin and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

55. An epidemiologic study published in the August 2014 online edition of *Neurology*

[4] Ali, A.K. Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis. Annals Epidemiol. 2014:24(4):279-85.

[5] *Id.*

provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.[6] The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).

Plaintiff Specific Facts

56. Plaintiff was prescribed Cipro by his healthcare providers on or about January 2004.

57. Plaintiff used the prescription as instructed.

58. Shortly after ingesting Cipro, Plaintiff began to experience a series of adverse reactions including the development of symptoms of peripheral neuropathy, pain, headaches, numbness, tingling, drop foot, as well as loss of strength and balance.

59. Plaintiff continues to suffer from pain, tingling and numbness sensations in his extremities, weakness, loss of strength and balance. Plaintiff can no longer participate in many activities without significant discomfort and pain.

60. Had Defendants properly disclosed the risks associated with Cipro, Plaintiff would have avoided the risk of peripheral neuropathy by not using the drug at all, and would not have suffered the injuries set forth with particularity herein.

61. As alleged herein, as a direct and proximate result of Defendants' negligent conduct, and the unreasonably dangerous and defective characteristics of the drug Cipro, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not

[6] Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. Neurology 2014; Epub 2014 Aug 22.

limited to, peripheral neuropathy. Plaintiff has further incurred losses and damages including pain and suffering, emotional distress, mental anguish, loss of enjoyment of life, loss of consortium, suffered economic loss, including loss of income and incurring significant expenses for medical care and treatment.

62. Plaintiff will continue to incur such losses, damages, and expenses in the future.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

63. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

64. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Cipro.

65. As a result of Defendants' actions, Plaintiff, and upon information and belief, Plaintiff's treating physicians were unaware and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein, and that those risks were the direct and proximate result of Defendants' acts and omissions.

66. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality, and nature of Cipro. Defendants were under a duty to disclose the true character, quality, and nature of Cipro because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

67. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants,

Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.

68. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

COUNT I

[Strict Liability]

69. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

70. Cipro was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Cipro failed to warn of the dangerous risks posed by Cipro, including the risk of developing irreversible peripheral neuropathy and other adverse symptoms associated with fluoroquinolone use.

71. At all times alleged herein, Cipro was defective and Defendants knew that their drug was to be used by consumers without inspection for defects. Moreover, Plaintiff, his prescribing physicians, and his health care providers neither knew nor had reason to know at the time of Plaintiff's use of Cipro of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

72. At all times alleged herein, Cipro was prescribed to and used by Plaintiff as

intended by Defendants and in a manner reasonably foreseeable to Defendants.

73. The designs of Cipro was defective in that the risks associated with using Cipro outweighed any benefits of the design. Any benefits associated with the use of Cipro were either relatively minor or nonexistent and could have been obtained by the use of other alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

74. The defect in design existed when the product left Defendants' possession.

75. At the time Cipro left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting their drug.

76. As a result of Cipro's defective condition, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT II

[Product Liability – Failure to Warn]

77. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

78. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Cipro, and through that conduct have knowingly and intentionally placed Cipro into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

79. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Cipro to Plaintiff and to his prescribing physicians. Additionally, Defendants expected the Cipro that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Cipro did in fact reach – prescribing physicians and consumers, including Plaintiff and his

prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

80. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective conditions of Cipro were due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

81. This defect caused serious injury to Plaintiff, who used Cipro in its intended and foreseeable manner.

82. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

83. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

84. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Cipro, namely irreversible peripheral neuropathy.

85. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Cipro caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Cipro use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

86. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

87. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

88. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

89. Had Defendants properly disclosed the risks associated with Cipro, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Cipro.

90. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT III

[Negligence]

91. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

92. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Cipro.

93. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

94. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of their fluoroquinolone product;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of the dangerous and defective characteristics of their fluoroquinolone product;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of the subject product;

g) In failing to perform appropriate post-market surveillance of the subject product;

h) In failing to adequately and properly test their fluoroquinolone product before and after placing it on the market;

i) In failing to conduct sufficient testing on their fluoroquinolone product which, if properly performed, would have shown that it had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiff and his healthcare providers that the use of their fluoroquinolone product carried a risk of developing irreversible peripheral neuropathy;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of their fluoroquinolone product; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from ingesting Cipro as described herein.

95. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

96. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT IV

[Breach of Express Warranty]

97. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

98. Before Plaintiff was first prescribed Cipro and during the period in which he used the drugs, Defendants expressly warranted that Cipro was safe.

99. Cipro did not conform to these express representations because the drug was not

safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

100. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT V

[Breach of Implied Warranty]

101. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

102. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Cipro, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit for the use for which it was intended.

103. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

104. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

105. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after he used it.

106. Contrary to the implied warranty for the subject product, Cipro was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

107. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VI

[Fraud]

108. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

109. Defendants made misrepresentations to Plaintiff, his prescribing physicians, and the healthcare industry regarding the safety and effectiveness of Cipro and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Cipro.

110. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Cipro had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiff, his prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996, Defendants and/or their predecessors were in possession of data demonstrating that Cipro increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Cipro before and after their product launch;

(c) Cipro was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Cipro increases the risk of irreversible peripheral neuropathy.

111. The misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

112. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, his prescribing physicians, and the healthcare industry.

113. Defendants made these false representations with the intent or purpose that Plaintiff, his prescribing physicians, and the healthcare industry would rely on them, leading to the use of Cipro by Plaintiff as well as the general public.

114. At all times herein mentioned, neither Plaintiff nor his physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, his physicians would not have prescribed and Plaintiff would not have taken the subject product.

115. Plaintiff, his prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Cipro that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true

dangers of Cipro. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

116. Defendants had a post-sale duty to warn Plaintiff, his prescribing physicians, and the general public about the potential risks and complications associated with Cipro in a timely manner.

117. Defendants made the representations and actively concealed information about the defects and dangers of Cipro with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Cipro as a treatment.

118. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Cipro and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VII

[Negligent Misrepresentation]

119. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

120. Defendants negligently and/or recklessly misrepresented to Plaintiff, his prescribing physicians, and the healthcare industry the safety and effectiveness of Cipro and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Cipro.

121. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Cipro had defects, dangers, and characteristics that were other than what Defendants had

represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, his prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996, Defendants and/or its predecessors were in possession of data demonstrating that Cipro increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Cipro before and after their product launch;

(c) Cipro was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Cipro increases the risk of irreversible peripheral neuropathy.

122. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

123. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, his prescribing physicians, and the healthcare industry.

124. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, his prescribing physicians, and the healthcare industry would rely on them, leading to the use of Cipro by Plaintiff as well as the general public.

125. At all times herein mentioned, neither Plaintiff nor his physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed

them to be true. Had they been aware of said facts, his physicians would not have prescribed and Plaintiff would not have taken the subject product.

126. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Cipro and relied on the absence of information regarding the dangers of Cipro which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

127. Defendants had a post-sale duty to warn Plaintiff, his prescribing physicians, and the general public about the potential risks and complications associated with Cipro and Levaquin in a timely manner.

128. Defendants made the representations and actively concealed information about the defects and dangers of Cipro with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Cipro as a treatment.

129. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Cipro and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VIII

[Fraudulent Concealment]

130. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

131. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and his

prescribing physicians would rely on such material representations.

132. Plaintiff and his prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

133. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, his prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and his prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and his prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

134. At all times herein mentioned, Defendants had a duty to Plaintiff, his prescribing physicians, and the general public to accurately inform them of risks associated with Cipro because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Cipro.

135. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Cipro at issue in this lawsuit, said breach or breaches constituting fraud because of the propensity to deceive others or constitute an injury to public interests or public policy.

136. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Cipro to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Cipro, he was placing himself at a significantly increased risk of developing irreversible peripheral neuropathy.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

PUNITIVE DAMAGES

137. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

138. At all times material hereto, Defendants knew or should have known that Cipro was inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

139. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Cipro.

140. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.

141. At all times material hereto, Defendants knew and recklessly disregarded the fact that Cipro and Levaquin causes the chronic illness irreversible peripheral neuropathy.

142. Notwithstanding the foregoing, Defendants continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

143. Defendants knew of their subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Cipro without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Cipro.

144. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable him to weigh the true risks of using Cipro against its benefits.

145. As a direct and proximate result of Defendants' willful, wanton, careless, reckless,

conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

146. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

RELIEF REQUESTED

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for Cipro;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff prays that the causes of action alleged herein be tried in this Court before a jury of his peers.

Dated: December 13, 2017

Respectfully Submitted,

By: Sindhu Daniel

Sindhu S. Daniel, Esq.
Attorney ID No. 77466
Baron & Budd, P.C.
3102 Oak Lawn Ave., Ste. 1100
Dallas, Texas 75219-4281
(214)521-3605
(214)520-1181 (fax)
sdaniel@baronbudd.com

Attorneys for Plaintiff

Pro Hac Vice Admission to be sought for:

Vance R. Andrus, Esq., CO 30764
David J. Wool, Esq., CO 44614
Andrus Wagstaff, PC
7171 W. Alaska Drive
Lakewood, CO 80226
Phone: (720) 208-9414
vance.andrus@andruswagstaff.com
David.wool@andruswagstaff.com

Counsel for Plaintiff